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EXAMINER	
SEVILLA, CHRISTIAN ANTHONY	
ART UNIT	PAPER NUMBER
3775	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,979	FELT ET AL.	
	Examiner	Art Unit	
	CHRISTIAN SEVILLA	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-13, and 15-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wildgoose et al. (US 5690636), hereinafter "Wildgoose."

Regarding claim 1, Wildgoose discloses the claimed invention including one or more apparatuses (10, 130, 139; Fig. 4) capable of preparing a joint to receive an implant, determining an appropriate implant size for a particular joint, determining an appropriate implant thickness, and inserting the implant into the joint. {col. 1, lines 10-15; col. 2, lines 42-50}.

Regarding claim 2, Wildgoose discloses a smoothing device (100) comprising a flat blade (101).

Regarding claim 4, Wildgoose discloses a device (10) "adapted for" use in the knee in order to determine a dimension between the anterior and posterior edges of the tibial surface (e.g. by sliding handle 12 relative to element 15; Fig. 1), while also providing a suitable depth measurement of the tibial depression (e.g. by distal end at 17 as a measuring instrument) at a point approximately midway between the raised anterior and posterior edges of the tibial plateau.

Regarding claim 5, Wildgoose discloses the joint sizing apparatus comprises a caliper (10), e.g. by sliding handle 12 and using element 15.

Regarding claim 6, Wildgoose discloses a plurality of trial implants (50) of one or more varying dimensions and/or configurations.

Regarding claim 7, Wildgoose discloses a plurality of knee implants {the trials are capable of being implants themselves} (50) of varying thickness to account for the ligament laxity in a particular knee joint and incorporate a design feature selected from the group consisting of number coded, bar coded, shape coded, tactile coded and/or visually coded.

Regarding claim 8, Wildgoose discloses the apparatus for inserting the implant comprises a plurality of opposing jaws (147; Fig. 4), together with a handle and a locking mechanism adapted to secure the jaws in position upon an implant (139).

Regarding claim 9, Wildgoose discloses one or more ancillary components {31; col. 3, line 39} adapted to secure an implant in the body.

Regarding claim 10, Wildgoose discloses a smoothing device {100; Fig. 3} for preparing one or more surfaces within an articulating joint site, the device comprising a substantially flat, straight or curved, blade having a proximal portion adapted to be hand held and/or attached to a powered surgical instrument, and a distal portion having at least one major surface provided with a texture adapted to smooth cartilage within the joint site, the joint sizing apparatus comprises a device (10; Fig. 1) adapted for use in the knee in order to determine a dimension between the anterior and posterior edges of the tibial surface, while also providing a suitable depth measurement of the tibial depression at a point approximately midway between the raised anterior and posterior edges of the tibial plateau, the apparatus for determining joint thickness comprises a

plurality of trial implants (139) of one or more varying dimensions and/or configurations, the apparatus for inserting the implant comprises a plurality of opposing jaws (147), together with a handle and a locking mechanism adapted to secure the jaws in position upon an implant, and one or more ancillary components are integrated into, and partially extending from, the implant to provide fixation, and one or more interpositional implants wherein at least one implant comprises a partially or fully preformed metallic and/or "polymeric" components {e.g. cement; col. 2, lines 42-50}, adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in apposition to opposing bone.

Regarding claim 11, Wildgoose discloses a smoothing device (100) for preparing one or more surfaces within an articulating joint site, the device comprising a substantially flat, straight or curved, blade having a proximal portion adapted to be hand held and/or attached to a powered surgical instrument, and a distal portion having at least one major surface provided with a texture adapted to smooth cartilage within the joint site.

Regarding claim 12, the device is "adapted for use" with one or more surfaces of the bones in the knee joint.

Regarding claim 13, the device is "adapted for use" in smoothing the condylar surface.

Regarding claim 15, Wildgoose discloses a distal portion of the blade is textured by providing either a plurality of closely spaced holes extending

through the width of the blade or a plurality of pegs or ridges (bottom edge of blade 101; Fig. 3) positioned upon the blade.

Regarding claim 16, Wildgoose discloses the device is "adapted for use" in a reciprocating saw instrument, and fabricated to retain a predetermined curved shape (distal edge of blade 101 is curved; Fig. 3).

Regarding claim 17, the device has an overall length of between "about" 100 mm and 150 mm, with a substantially distal portion having a length of between "about" 20 mm and about 40 mm.

Regarding claim 18, the blade width is between "about" 5 mm and "about" 10 mm, and has a thickness of between "about" 0.3 mm and "about" 5 mm.

Regarding claim 19, the proximal portion of the device is provided in the form of generally circular shaft (103), adapted to be fixably and releasably positioned within a powered surgical instrument (11).

Regarding claim 20, the powered surgical instrument is adapted to operate the blade at an excursion distance of between about 0.5 mm and about 10 mm.

Regarding claim 21, Wildgoose discloses a joint sizing apparatus (10; Fig. 3) for sizing a joint for use in the system of claim 1, adapted for measuring one or more dimensions associated with the knee.

Regarding claim 22, the device is "adapted to measure" (as by sliding something between handle 10 and stop 20) one or more dimensions selected from the group consisting of an anterior-posterior dimension, a medial-lateral dimension, and a height/depth dimension.

Regarding claim 23, the device is "adapted for use" in the knee and can be used to determine a dimension between the anterior and posterior edges of the tibial surface, while also providing a suitable depth measurement of the tibial depression (e.g. by using distal surfaces at 17 to measure a length) at a point approximately midway between the raised anterior and posterior edges of the tibial plateau.

Regarding claim 24. Wildgoose discloses the apparatus comprises a caliper (10).

Regarding claim 25, Wildgoose discloses the caliper comprises a handle assembly (12, 15) and a gauge portion (surface of stop 15 that faces towards handle 12) adapted to engage the posterior edge of the tibial plateau and without interference from the femoral condyle.

Regarding claim 26, Wildgoose discloses a slide (outer surface of handle12, Fig. 1) having a raised contact end portion which translates back and forth relative to a rule (14) that can be positioned against the anterior portion of the tibia.

Regarding claim 27, Wildgoose discloses a probe (curved portion of handle 12 closest to stop 15; Fig. 1) positioned along the length of the rule, and optionally movable laterally thereto, in order to measure the depth of any indentation, or bowl shape that the tibial surface may have.

Regarding claim 28, Wildgoose discloses the probe is mounted on a slide (outer surface of element 12, Fig. 1), moveable longitudinally with the axis of the rule, to permit it to be adjusted to make depth measurements in various locations.

Regarding claim 29, Wildgoose discloses the anterior-posterior dimension of the tibial surface can be read from the rule as the distance between the point contacting the posterior tibial surface edge and a point contacting the anterior edge.

Regarding claim 30, Wildgoose discloses a caliper (10) adapted for measuring one or more dimensions associated with the knee, including to measure one or more dimensions selected from the group consisting of an anterior-posterior dimension, a medial-lateral dimension, and a height/depth dimension.

Regarding claim 31, Wildgoose discloses an apparatus (50) for determining joint thickness for use in the system of claim 1.

Regarding claim 32, Wildgoose discloses a plurality of trial implants (50, 87, 139) of one or more varying dimensions and/or configurations {col. 2, lines 10-13}.

Regarding claim 33, Wildgoose discloses the plurality of trial implants comprises a plurality of knee implants of varying thickness to account for the ligament laxity in a particular knee joint.

Regarding claim 34, Wildgoose discloses the respective trial implants are designed in a manner that eases their selection and use, while serving to minimize error.

Regarding claim 35, Wildgoose discloses the components are designed in a manner selected from the group consisting of number coded, bar coded, shape coded, tactile coded and/or visually coded {the trial implants 50 are differently sized, therefore they are visually coded; col. 4, lines 31-37}.

Regarding claim 36, Wildgoose discloses an apparatus (130; Fig. 4) for inserting an interpositional arthroplasty implant for use in the system of claim 1.

Regarding claim 37, Wildgoose discloses the apparatus is "adapted to" firmly hold an interpositional knee implant {col. 7, lines 10-15}.

Regarding claim 38, the apparatus comprises a plurality of opposing jaws (147; Fig. 4).

Regarding claim 39, the apparatus further comprises a handle (all outer surfaces of the apparatus 130) and a locking mechanism (134) adapted to secure the jaws in position upon an implant.

Regarding claim 40, the first and second jaws are pivotally coupled to the handle, as the jaws are capable of being pivoted.

Regarding claim 41, Wildgoose discloses a portion (149) adapted to bias the handle {the portion biases release button 135 of handle 130; col. 7, lines 19-24} in an open position.

Regarding claim 42, Wildgoose discloses the apparatus is "adapted to hold" an anterior portion (148) of an implant (139) while a posterior portion of the implant is inserted between a medial condyle of a femur and tibial plateau of a tibia.

Regarding claim 43, Wildgoose discloses one or more ancillary components (cement; col. 3, lines 50-54) adapted to secure an implant in the system of claim 1.

Regarding claim 44, Wildgoose discloses the at least one ancillary component

is integrated into, since Wildgoose discloses the cement is provided around the keel of the tibial implant {col. 3, lines 19-24}, and partially extending from, the implant to provide anterior fixation.

Regarding claim 45, Wildgoose discloses the ancillary component comprises one or more protrusions adapted to be attached to either soft tissue and/or bone at the joint site to improve fixation.

Regarding claim 46, Wildgoose discloses the protrusions are selected from one or more separate components (the bone cement) for securing the implant to the joint site, selected from the group consisting of adhesives.

Regarding claim 47, Wildgoose discloses one or more interpositional implants (50, 87, 139).

Regarding claim 48, Wildgoose discloses a partially or fully preformed metallic and/or polymeric components, specifically cement (col. 3, lines 23), adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in apposition to opposing bone.

Regarding claim 49, the implant comprises a knee implant {col. 4, lines 31-34}.

Regarding claim 50, the implant (87; Fig. 87) provides a femoral glide path and convexity (combined surfaces of 92 and 84) of the tibial surface of the implant, together with a posterior medial lip (94).

Regarding claim 51, the polymeric components are provided in the form of a single preformed component comprising a biomaterial partially or completely cured in

an ex vivo mold. Specifically the polymeric component (cement) is partially cured in an ex vivo mold (the container which holds the cement prior to in vivo application).

Regarding claim 52, the implant comprises tibial projection(s) {a standard or cruciform keel of an implant; col. 3, lines 21-24} "adapted to" catch the posterior portion of the tibial plateau by extending over the rim of the tibial plateau distally.

Regarding claim 53, the preformed component (cement after it has cured in vivo) has dimensions "on the order of" between about 30 to about 60 mm in the anterior-posterior dimension, between about 20 mm to about 40 mm in the medial-lateral dimension, and a maximum thickness, at the posterior lip, of between about 8 mm and about 20 mm, or about 3 mm to about 10 mm greater than the thickness of the implant at the center.

Regarding claim 54, the implant further comprises at least one ancillary component {a standard or cruciform keel of an implant; col. 3, lines 21-24} integrated into, and partially extending from, the implant to provide anterior fixation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wildgoose in view of Freedman (US 4185634).

Wildgoose fails to disclose the blade (101) is fabricated from surgical stainless steel.

Attention however is directed to Freedman, which teaches a medical device {col. 2, lines 6-7} wherein a blade may be constructed from surgical stainless steel.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to have constructed the blade from surgical stainless steel since doing so would have provided a blade with sufficient hardness to cut bone.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THOMAS C. BARRETT can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN SEVILLA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775